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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MARKET PHARMACY, INC.; AHCS MENTAL HEALTH & WELLNESS, INC. d/b/a BERRY & SWEENEY PHARMACY; COMMUNITY PHARMACY GROUP, INC. d/b/a GLESENER PHARMACY; PRESCRIPTIONS PLUS, INC. d/b/a SUPER RITE DRUGS; MIKMARA, INC. d/b/a ALLEN PHARMACY; and PACIFIC PHARMACY GROUP, INC. d/b/a VALENCIA PHARMACY,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX AZAR; CENTERS FOR MEDICARE AND MEDICAID SERVICES, and SEEMA VERMA,

Defendants.

Case No.

COMPLAINT

Plaintiffs Market Pharmacy, Inc.; AHCS Mental Health & Wellness, Inc. d/b/a Berry & Sweeney Pharmacy; Community Pharmacy Group, Inc. d/b/a Glesener Pharmacy; Prescriptions Plus, Inc. d/b/a Super Rite Drugs; Mikmara, Inc. d/b/a Allen Pharmacy; and Pacific Pharmacy Group, Inc. d/b/a Valencia Pharmacy (collectively "Plaintiffs"); by way of Complaint against Defendants, the United States Department of Health and Human Services ("HHS"), Alex Azar, solely in his official capacity as Secretary of the United States Department of Health and Human Services; the Centers for Medicare and Medicaid Services ("CMS"); and Seema Verma solely in her capacity as Administrator of the Centers for Medicare and Medicaid Services, allege as follows:

PRELIMINARY STATEMENT

1. California's state Medicaid program, Medi-Cal, intends to implement a new reimbursement structure that will significantly reduce the total reimbursement paid to pharmacies dispensing specialty medications, medications which often times treat California's neediest and most vulnerable residents. As described in detail below, California has chosen to reduce the amount it pays pharmacies for their ingredient costs to purchase specialty medications, and has similarly chosen to reimburse pharmacies with an unreasonably low "professional dispensing fee" when dispensing specialty medications. California intends to implement this rule despite the fact that pharmacies operating in California that primarily dispense specialty medications already have razor-thin margins.

2. Plaintiffs, a collection of independent pharmacies located in California that primarily dispense specialty medications ("Specialty Pharmacies"), have filed this action to enjoin the implementation of these new Medicaid reimbursement rates. In doing so, Plaintiffs rely on federal law, which requires state Medicaid programs to establish reimbursement rates that cover pharmacies' costs to purchase prescription drugs as well as costs associated with dispensing those drugs to Medicaid patients.

3. As set forth below, California failed to properly gather data with respect to the impact its proposed reimbursement rates would have on Specialty Pharmacies and, in fact, chose to remove data received from Specialty Pharmacies from its analysis. Notwithstanding the impropriety of the tactics used by California to adopt its Medicaid pricing structure for pharmacy reimbursement, the Defendants approved the reimbursement structure. Defendants' approval of this plan, however, is a violation of the Administrative Procedure Act, as the Defendants' approval was arbitrary, capricious, an abuse of discretion, and not in accordance with applicable federal law.

4. Unless this Court enters a preliminary injunction to enjoin the implementation of these modified reimbursement rates, many California Specialty Pharmacies will elect to withdraw from participating in Medi-Cal, resulting in far less access for Medicaid beneficiaries to obtain their life saving specialty medications.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over the claims presented in this action pursuant to 28 U.S.C. § 1331, as the claims derived from the Administrative Procedure Act, 5 U.S.C. § 706 *et seq*.

6. This Court has personal jurisdiction over Defendants because the Defendants carry out their federally-mandated obligations in the State of California, and the committed acts giving rise to this lawsuit occurred principally within the State of California.

7. Venue is proper in this District pursuant to 28 U.S.C. § 1391(e).

THE PARTIES

8. Plaintiff Market Pharmacy, Inc. is a corporation organized and existing under the laws of California with its principal place of business as 9250 Reseda Boulevard, Unit 2C, Northridge, California, 91324.

9. Plaintiff AHCS Mental Health & Wellness, Inc. d/b/a Berry & Sweeney Pharmacy is a corporation organized and existing under the laws of California with its principal place of business as 1377 North Fair Oaks Avenue, Pasadena, California 91103.

10. Plaintiff Community Pharmacy Group, Inc. d/b/a Glesener Pharmacy is a corporation organized and existing under the laws of California with its principal place of business as 321 North Citrus Avenue, Covina, California 91723.

11. Plaintiff Prescriptions Plus, Inc. d/b/a Super Rite Drugs is a corporation organized and existing under the laws of California with its principal place of business as 14425 Burbank Boulevard, Van Nuys, California, 91401.

12. Plaintiff Mikmara, Inc. d/b/a Allen Pharmacy is a corporation organized and existing under the laws of California with its principal place of business as 1141 6th Avenue, San Diego, California 91201.

13. Plaintiff Pacific Pharmacy Group, Inc. d/b/a Valencia Pharmacy is a corporation organized and existing under the laws of California with its principal place of business as 23550 Lyons Avenue, #111, Newhall, California 91321.

14. Defendant HHS is a cabinet department charged with the administration of the Medicaid program.

15. Defendant Azar is sued solely in his official capacity as Secretary of HHS.

16. Defendant CMS is the agency within HHS charged with the administration of the Medicaid program.

17. Defendant Verma is sued solely in her official capacity as Administrator of CMS.

FACTS COMMON TO ALL COUNTS

A. BACKGROUND OF SPECIALTY PHARMACY

18. Plaintiffs are a group of independent Specialty Pharmacies. Specialty Pharmacies, such as the Plaintiffs, dispense costly and complex treatments for

serious illnesses. The complexity of the patients' illnesses requires Specialty Pharmacies to provide services distinct from those provided at non-specialty retail pharmacies. Specifically, the process of acquiring, storing, handling, and gaining approval to dispense specialty medications is far more complex than typical medications obtained at retail pharmacies.

19. As an initial matter, specialty medications are incredibly costly. Specialty medications are on the cutting edge of medical care and treatment for diseases that are among the most devastating to the population, including cancer, hepatitis, behavioral and mental health, and HIV. Many specialty medications, including behavioral health medications, have acquisition costs in the thousands of dollars and pharmacies dispensing these medications have very small profit margins.

20. Some specialty medications require special handling when storing and delivering to patients. Many specialty medications require cold-chain storage and delivery, as the medication needs to remain at a constant cold temperature to ensure proper efficacy. This special handling requires capital-intensive storage facilities at the Specialty Pharmacy, special and costly packaging when delivering the medication, and close coordination with the patient to ensure the medication is administered or stored properly once delivered.

21. Further, Plaintiffs work closely with prescribers and insurance companies to aid in the coverage approval process, sometimes referred to as "prior approval" or Treatment Authorization Requests ("TARS"). Many specialty medications require more than a valid prescription from a provider, such as prior approval from the patient's insurance company or from Medi-Cal before the patient can begin treatment. Plaintiffs work closely with prescribers to ensure patients requiring specialty medications receive timely prior approval and Medi-Cal authorization.

22. In addition, patient education, coordination and communication are key components of Plaintiffs' operation. Patients must be educated on how to administer medication, such as self-injectable drugs stored in prefilled syringes. Plaintiffs must closely coordinate with patients to ensure medication is either picked up or delivered at a precise time to ensure proper handling of the medication, as previously mentioned. Plaintiffs must closely communication with patients and prescribers to ensure that each patient closely adheres to their treatment regiments, as many specialty medications must be administered in a specific fashion over a period of time to remain effective in treating a medical condition. For example, certain types of Hepatitis C can be successfully cured through proper treatment over a 12-week period. However, if a patient does not precisely adhere to the treatment regimen over that extended period of time the treatment may be ineffective.

23. Independent Specialty Pharmacies, such as the Plaintiffs, are essential to the healthcare delivery system in that they provide unique and essential services that standard mail order and large pharmacies simply cannot. Plaintiffs serve the lowest functioning and highest risk population within our healthcare ecosystem—the homeless, indigent, parolees, violent criminals, and those suffering from opioid epidemic—a majority of which are covered by Medi-Cal. By way of example, upon information and belief over 70% of California's mental health patients are served by independent Specialty Pharmacies. This population of high-risk patients often do not have transportation to go to Specialty Pharmacies and are in need of greater assistance to navigate their health care requirements. Plaintiffs, and other Specialty Pharmacies in California, are the only pharmacies that offer these "high touch" services on such an involved and attentive basis.

B. BACKGROUND OF MEDICAID

24. Medicaid is a joint federal and state healthcare benefits program created under Title XIX of the Social Security Act. Medicaid aims to provide health care to indigent and needy individuals and families in the United States.

25. The Medicaid program is jointly financed by the federal and state governments, and is administered by the states.

26. In order to receive matching funds from the federal government, states must agree to administer their Medicaid program in compliance with the applicable federal Medicaid laws and regulations. *See* 42 U.S.C. § 1396 *et seq.*

27. Federal law requires that each state specify a single State Agency established or designated to administer or supervise the administration of the state's Medicaid program. 42 C.F.R. § 431.10. The State Agency must make rules and regulations to administer the state's Medicaid plan, and is responsible for determining eligibility for Medicaid benefits in accordance with federal law.

28. Each State Agency must submit for approval a "State Plan" to CMS, which is a comprehensive written statement describing the nature and scope of the state's Medicaid program and gives assurances that the state's Medicaid program will be administered in accordance with applicable federal law. 42 C.F.R. § 430.10.

29. If a State Agency intends to make an amendment to its State Plan, it must submit a "State Plan Amendment." State Plan Amendments are appropriate when there is either (1) a change in federal law, regulations, policy interpretations, or court decisions; or (2) material changes in the state's law, organization, or policy, or in the state's operation of the Medicaid program. 42 C.F.R. § 430.12(c).

30. CMS is then tasked with reviewing the State Plan Amendment to ensure that the state's Medicaid program will remain in compliance with all applicable law. CMS's Regional Administrator will then notify the State Agency

whether the State Plan Amendment was approved or disapproved. 42 C.F.R. § 423.16.

31. One such applicable federal law that CMS is tasked with ensuring any State Plan Amendment abides by is 42 U.S.C. § 1396a(a)(30)(A) ("Section 30A"), which requires each State Plan:

> ***to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general public in the geographic area.***

(emphasis added).

32. When a State Agency is proposing changes to the State's ingredient cost reimbursement or professional dispensing fee reimbursement, federal law requires that the total reimbursement to the pharmacy provider is in accordance with [Section 30A]. 42 C.F.R. § 447.518(d).

33. Further, federal law requires that "States must provide adequate data such as a State or national survey of retail pharmacy providers or other reliable data other than a survey to support any proposed changes to either or both of the components of the reimbursement methodology. States must submit to CMS the proposed change in reimbursement and the supporting data through a State plan amendment through the formal review process." 42 C.F.R. § 447.518(d).

C. OUTPATIENT PRESCRIPTION DRUG REIMBURSEMENT IN MEDICAID

34. Until recently, State Agencies were required to reimburse pharmacies for the dispensing of drugs based on two figures: (1) reimbursement for the drug ingredient cost and (2) reimbursement for the cost of dispensing.

35. Federal regulations required that reimbursement for drug ingredient costs was to be no more than the State Agency's best estimate of the acquisition cost for a drug.

36. A drug's estimated acquisition cost, or "EAC" is defined as the state's best estimate of the prices generally and currently paid by providers for a drug marketed or sold by manufacturers or labelers in the package size of the drug most frequently purchased by providers.

37. In order to obtain EAC for dispensed drugs, many State Agencies utilized published drug pricing benchmarks, such as the Average Wholesale Price ("AWP"), Wholesale Acquisition Cost ("WAC"), or Average Sales Price ("ASP").

38. For instance, California's State Plan has determined that the EAC for drugs dispensed to California Medicaid beneficiaries is roughly AWP -17%.

39. The second part of the reimbursement formula—the cost of dispensing, or "dispensing fee"—is typically a nominal fee. For instance, California's current dispensing fee is $7.00.

40. The reimbursement rates currently utilized by California's State Plan, consisting of the ingredient cost plus a dispensing fee, lead to razor-thin margins for Specialty Pharmacies dispensing specialty medications, with such Specialty Pharmacies breaking even or making just a marginal profit each time they dispense a specialty drug to a Medicaid beneficiary.

D. CMS ADOPTS NEW PRICING REGULATIONS FOR THE DISPENSING OF DRUGS IN MEDICAID

41. In February 2016, CMS promulgated a new regulation that drastically changed the reimbursement structure for pharmacies participating in the Medicaid program (the "CMS Rule"). 81 Fed. Reg. 5170 (Feb. 1, 2016).

42. The CMS Rule required states to base ingredient cost reimbursement on actual acquisition cost of the drug, or "AAC," as opposed to EAC. 42 C.F.R. §§ 447.502, 447.512(b).

43. The CMS Rule also required each State Agency to establish a new "professional dispensing fee" sufficient to cover a list of pharmacy costs associated with dispensing drugs, including:

a. reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage,

b. performing drug utilization review and preferred drug list review activities,

c. measurement or mixing of the covered outpatient drug,

d. filling the container,

e. beneficiary counseling,

f. physically providing the completed prescription to the Medicaid beneficiary,

g. delivery,

h. special packaging, and

i. overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.

44. CMS required that each state submit a State Plan Amendment in order to implement the aforementioned reimbursement changes by April 1, 2017.

45. CMS allowed the states to implement an AAC model of reimbursement based on a number of pricing methodologies. CMS indicated that states may develop an AAC model of reimbursement based on data received from a state survey of retail pharmacy providers' pricing. States may also develop an AAC model of reimbursement based on published compendia prices, such as WAC.

46. However, in an effort to establish uniform AAC reimbursement, CMS created the National Average Drug Acquisition Cost ("NADAC") pricing benchmark. The NADAC pricing benchmark was designed to represent a national pricing methodology based upon an average of voluntarily-submitted retail pharmacy acquisition costs for a number of drugs.

47. To develop NADAC, CMS contracted with Myers and Stauffer, LC, a public accounting firm, to conduct surveys of pharmacy ingredient prices. The surveys collect acquisition costs and invoice purchase prices for outpatient drugs purchased by predominately chain retail pharmacies and independent retail pharmacies.

48. Specifically, on a monthly basis Myers and Stauffer LC collects acquisition date from a random sample of pharmacies selected from all 50 states and the District of Columbia. The pharmacy entities surveyed are independent and chain retail community pharmacies.

49. Critically, many Specialty Pharmacies are ***excluded*** from the surveys. Myers and Stauffer identifies Specialty Pharmacies based on their classification in the National Council for Prescription Drug Programs ("NCPDP") database, as well as whether the pharmacy is URAC certified in specialty pharmacy. If a Specialty Pharmacy is classified as such in the NCPDP database or is URAC certified, that pharmacy's data will not be considered by Myers & Stauffer when developing a NADAC price for a specialty medication.

50. The survey filled out by pharmacies participating in the NADAC survey includes the following information: (1) the type of medication, (2) the unit price paid by the pharmacy, (3) the invoice date, and (4) the quantity purchased. Myers and Staffer, LC collect the documentation and then create the NADAC pricing.

51. CMS has instructed Myers and Staffer, LC to require at least five cost observations for each drug in order to determine a NADAC ingredient cost reimbursement.

52. Despite NADAC excluding the participation of Specialty Pharmacies from its surveys, NADAC nevertheless establishes reimbursement rates for specialty medications based on data collected from retail non-specialty pharmacies. The data received from retail non-specialty pharmacies regarding the

costs of acquiring and dispensing specialty medications is oftentimes misrepresentative of such costs for Specialty Pharmacies, resulting in many Specialty Pharmacies being reimbursed at unreasonably low rates when dispensing specialty medications to Medicaid patients.

53. If NADAC pricing is applied, based on a matrix that reflects the acquisition cost of non-specialty pharmacies or chain drug stores (many of which have lower acquisition costs due to more favorable contracts with wholesalers) or the acquisition cost of hospitals who typically purchase medications in a greater scale, it will become nearly impossible for independent Specialty Pharmacies, such as Plaintiffs, to continue to stay solvent, let alone provide the "high touch" services that improve patient outcomes.

E. CALIFORNIA CONDUCTS STUDY AND ULTIMATELY ADOPTS NADAC PRICING TO COMPLY WITH AAC REQUIREMENT

54. In order to issue its State Plan Amendment to CMS in accordance with the CMS Rule, California's Department of Health Care Services ("DHCS") engaged Mercer Government Human Services Consulting ("Mercer") to conduct a study on outpatient pharmacy provider costs associated with purchasing and dispensing outpatient prescription drugs to California Medicaid members.

55. To conduct the study, Mercer issued two different surveys to California pharmacies: (1) a survey which collected data necessary to calculate the average cost of dispensing a prescription (the "Dispensing Fee Survey"), and (2) a survey aimed at identifying pharmacy purchase prices for brand and generic drugs (the "Ingredient Cost Survey").

56. With regard to the Dispensing Fee Survey, Mercer issued surveys to 5,644 pharmacies and only received usable information from 2,562 pharmacies. Notably, Mercer only received data from three (3) Specialty Pharmacies, and opted not to include the data for purposes of determining the appropriate Dispensing Fee due to the "small number of responses." Indeed, Mercer's final

report indicates that "costs of dispensing for…specialty pharmacies could not be estimated because of the low number of responses for these pharmacy types."

57. Mercer did, however, obtain data from non-specialty retail pharmacies regarding the costs associated with dispensing specialty drugs in its Dispensing Fee Survey. However, acquisition costs and dispensing costs associated with dispensing specialty medications are far different between non-specialty retail pharmacies and Specialty Pharmacies. This is due to a number of realities, including buying power, the level of patient care and "high touch" services provided by Specialty Pharmacies, and overall differing dispensing portfolios.

58. Notably, Mercer's final report states that:

> A number of additional variables were included in the survey to explore specialty prescription costs. Unfortunately, these appeared to introduce irreconcilable incongruities between specialty revenue and prescription sales and may be a cause of many of the ***93 pharmacies that reported higher costs of dispensing than total sales***. In any case, introduction of these variables into the regression did not produce intuitive results.

(emphasis added).

59. Despite acknowledging that reports by pharmacies that dispensing specialty medications results in "higher costs of dispensing than total sales," Mercer's final report recommended three proposed Dispensing Fees applicable to retail pharmacies and Specialty Pharmacies alike, including the two tier Dispensing Fee that would ultimately be adopted by DHCS, as further described below.

60. With regard to the second survey issued by Mercer—the Ingredient Cost Survey, Mercer surveyed 600 pharmacies and had 372 pharmacies participate.

61. After reviewing the data, Mercer proposed three proposed methods of obtaining the appropriate ingredient cost, including the adoption of NADAC pricing for brand and generic products, which was ultimately be adopted by DHCS.

62. Critically, in its final report Mercer indicated that "the main challenge with [the adoption of NADAC pricing] is the lack of NADAC rates for many specialty drugs and supplies."

63. Upon receipt of Mercer's final report dated January 4, 2017, DHCS submitted its State Plan Amendment to CMS on May 30, 2017, which proposed to change California's Medicaid reimbursement structure in order to comply with the Medicaid Rule.

64. DHCS's State Plan Amendment set California's Medicaid Ingredient Cost as the lesser of:

a. The NADAC of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0%, or

b. The Federal Upper Limit, or

c. The Maximum Allowable Ingredient Cost.

65. The DHCS State Plan Amendment adopted Mercer's recommendation and utilized a two tier approach for the Professional Dispensing Fee:

a. Less than 90,000 claims submitted by the pharmacy = $13.20, or

b. 90,000 or more claims = $10.05.

66. California's DHCS adopted the aforementioned Ingredient Cost and Professional Dispensing Fee structure despite Mercer's final report indicating that it did not receive sufficient data to determine an appropriate dispensing fee for Specialty Pharmacies and that many specialty medications do not have NADAC pricing.

67. By way of correspondence dated August 25, 2017, CMS approved DHCS's State Plan Amendment.

68. Notably, the changes to California's Medicaid reimbursement structure, once implemented through the State Plan Amendment, will be ***retroactively*** applied back to April 1, 2017. While DHCS has yet to implement its

State Plan Amendment modifying the Medicaid reimbursement, once the State Plan Amendment becomes effective, the new Ingredient Cost and Professional Dispensing Fee reimbursement structure will be retroactively applied to every Medicaid claim submitted by participating pharmacies from April 1, 2017 to the effective date. Said another way, DHCS is going to "claw back" the difference in reimbursement to participating pharmacies once the State Plan Amendment is enacted.

69. Upon information and belief, California's State Plan Amendment will be enacted in late 2018.

F. THE IMPACT CALIFORNIA'S STATE PLAN AMENDMENT WILL HAVE ON PLAINTIFFS

70. The impact California's State Plan Amendment will have on Plaintiffs is nothing short of devastating.

71. Indeed, the failure of California's DHCS as well as the NADAC pricing benchmark to incorporate acquisition costs and dispensing costs of ***Specialty Pharmacies***, despite setting reimbursement rates of ***specialty medications***, will result in dramatically decreased reimbursement rates, as the data relied upon to set the NADAC pricing benchmark for these specialty medications is only provided by non-specialty retail pharmacies, which have better margins due to the offering of more generic, less patient-centric services and increased buying power and leverage.

72. In addition, NADAC pricing is based on national averages of acquisition cost for pharmacies, and does not account for California's higher cost of business, such as higher rent prices, higher wages, higher Worker'

73. Once California implements its State Plan Amendment, Plaintiffs, along with countless other Specialty Pharmacies located in California, will see a dramatic decrease in their reimbursement rates, such that Plaintiffs will now be reimbursed below their actual cost of dispensing the medication. In other words,

Plaintiffs will not make any profit in connection with dispensing a host of specialty medications to California Medicaid beneficiaries, but rather lose money each time they dispense said medications.

74. For instance, about 64% of Market Pharmacy's business is dedicated to serving California Medicaid patients.

75. Currently (prior to the implementation of California's State Plan Amendment), Market Pharmacy is reimbursed AWP -17% plus a dispensing fee of $7.00 for each prescription dispensed.

76. However, once California's State Plan Amendment is implemented, Market Pharmacy will be reimbursed in accordance with the NADAC rate of each dispensed medication, plus a $10.00 professional dispensing fee.

77. This change will result in Market Pharmacy's reimbursement rates being insufficient to cover Market Pharmacy's medication acquisition cost and overhead.

78. By way of example, Market Pharmacy anticipates losing approximately $600,000 per year if the pharmacy maintains dispensing specialty drugs to California Medicaid patients.

79. Even worse, due to the retroactive application of California's State Plan Amendment, Market Pharmacy will have approximately $800,000 – $1,000,000 clawed back in connection with claims submitted from April 1, 2017 to the date of implementation.

80. This negative impact is consistent among all of the Plaintiffs.

81. Simply put, the reimbursement rates set forth in California's State Plan Amendment fail to reimburse Plaintiffs their "actual acquisition cost" but rather reimburse Plaintiffs far below their cost of dispensing specialty medications.

82. As a result of California's State Plan Amendment, Plaintiffs, along with many other Specialty Pharmacies located in California, will stop filling

prescriptions for Medi-Cal beneficiaries due to being reimbursed below the cost of dispensing the medication. This will result in California Medicaid patients losing access access to their life-saving medications and to the critical and unique services that independent Specialty Pharmacies like the Plaintiffs provide.

FIRST CAUSE OF ACTION

VIOLATION OF ADMINISTRATIVE PROCEDURE ACT

5 U.S.C. §§ 701-706

83. Plaintiffs hereby incorporate by reference the prior paragraphs of this Complaint as though fully set forth herein.

84. Under the federal Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706, courts must overturn agency action that is arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with the law.

85. CMS's approval of California's State Plan Amendment on August 25, 2017 constitutes "agency action" as defined at 5 U.S.C. § 551(13).

86. CMS's approval of California's State Plan Amendment is invalid under the APA because it is arbitrary, capricious, an abuse of discretion, and otherwise inconsistent with governing law.

87. More specifically, California DHCS, and thus CMS, failed to conduct an analysis of whether the State Plan Amendment's reimbursement rates for Specialty Pharmacies dispensing specialty medications were sufficient to assure that Medi-Cal beneficiaries would have the same access to care as the general public in the same geographic area. In fact, the Mercer Report, of which both California DHCS and CMS relied upon to approve the new reimbursement rates, indicated that "costs of dispensing for . . . specialty pharmacies could not be estimated because of the low number of responses for these pharmacy types."

88. Thus, it is a factual impossibility for CMS to have properly considered whether the reimbursement rates implemented by California's State Plan Amendment would be sufficient to ensure that Medi-Cal beneficiaries would have

the same access to specialty medications as the general public as required by Section 30A.

89. Further, the NADAC pricing benchmark's reliance upon data submitted by non-specialty retail pharmacies to establish appropriate reimbursement rates for specialty medications widely dispensed by Specialty Pharmacies is entirely improper and leads to unreasonably low reimbursement rates which are oftentimes lower than Plaintiffs' cost of dispensing the medications.

90. As a result, CMS's approval of California's State Plan Amendment is invalid under the APA because it is arbitrary, capricious, an abuse of discretion, and a flagrant violation of governing law, i.e. Section 30A.

SECOND CAUSE OF ACTION

(DECLARATORY RELIEF)

91. Plaintiffs hereby incorporate by reference the prior paragraphs of this Complaint as though fully set forth herein.

92. An actual and justiciable controversy exists between Plaintiffs and the Defendants regarding whether California's State Plan Amendment complied with the requirements of Section 30A of the Federal Medicaid Act. Plaintiffs contend that CMS's approval of California's State Plan Amendment was arbitrary, capricious, an abuse of discretion, and not in accordance with applicable law.

93. Accordingly, pursuant to 28 U.S.C. § 2201, Plaintiffs request this Court to declare that the reimbursement rates set forth by California's State Plan Amendment and approved by the Defendants are invalid and unlawful pursuant to Section 30A.

94. No administrative appeal process or other administrative remedy is available to Plaintiffs to challenge the reimbursement rates set forth in California's State Plan Amendment.

WHEREFORE, Plaintiffs pray for judgment as follows:

A. For an Order declaring that Defendants' approval of California's State Plan Amendment was arbitrary, capricious, an abuse of discretion, and not in accordance with applicable law.

B. For an Order setting aside Defendants' approval of California's State Plan Amendment.

C. For a Declaration that Defendants' approval of California's State Plan Amendment was contrary to law and violated Section 30A of the Medicaid Act;

D. For the costs of suit, including reasonable attorneys' fees incurred by Plaintiffs;

E. Such other relief as deemed just and proper by this Court.

Dated: September 28, 2018

Respectfully submitted,

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MICHAEL L. LAVETTER

— and —

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